

2009 DRAFTING REQUEST

Bill

Received: **11/26/2008**

Received By: **rryan**

Wanted: **As time permits**

Identical to LRB:

For: **Administration-Budget (608) 266-2214**

By/Representing: **Palchik**

This file may be shown to any legislator: **NO**

Drafter: **tdodge**

May Contact:

Addl. Drafters:

Subject: **Health - public health**

Extra Copies:

Submit via email: **NO**

Pre Topic:

DOA:.....Palchik, BB0237 -

Topic:

Cancer researcher access to cancer registry data

Instructions:

See attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	tdodge 12/05/2008	wjackson 12/05/2008		_____			State Crime
/1	tdodge 01/30/2009	wjackson 01/30/2009	rschluet 12/08/2008	_____	sbasford 12/08/2008		State Crime
/2			jfrantze 01/30/2009	_____	cduerst 01/30/2009		

FE Sent For:

<END>

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/?	tdodge	1 wj 12/5		_____ _____			

FE Sent For:

<END>

2009-11 Budget Bill Statutory Language Drafting Request

- Topic: Access to Cancer Information/Cancer Registry
- Tracking Code: BB0237
- SBO team: Health and Insurance
- SBO analyst: Laurie Palchik
• Phone: 266-2214
• Email: laurie.palchik@wisconsin.gov
- Agency acronym: DHS
- Agency number: 435
- Priority (Low, Medium, High): Medium

Intent: Allow cancer researchers access to cancer registry data.

- 1) Use existing draft legislation LRB-3843 from the 2007-2007 Bill Session – SB 415.
- 2) Remove GPR appropriation and create a PR continuing appropriation against which the department can set fees in administrative rule and collect revenue.
- 3) Allow the department broad flexibility for fee setting.
- 4) Leave penalty language as previously drafted regarding privacy and confidentiality matters of patient records.
- 5) Remove the GPR FTE position under Section 12 Nonstatutory provisions.

Insert pretopic

In: 12/05/08

TJD

WLJ

0956

2007 SENATE BILL 415

Insert

LPS: Please
DNF

January 24, 2008 – Introduced by Senators SULLIVAN, KREITLOW, SCHULTZ, ROBSON, MILLER, COWLES, LEHMAN, KAPANKE, OLSEN, RISSER, ROESSLER, PLALE, HANSEN, LASSA, DARLING, TAYLOR and COGGS, cosponsored by Representatives SHILLING, WIECKERT, VRUWINK, SHERIDAN, MUSSER, RICHARDS, DAVIS, VAN AKKEREN, SUDER, HEBL, JESKEWITZ, BLACK, POPE-ROBERTS, MASON, MURTHA, GRIGSBY, HILGENBERG, YOUNG, SEIDEL, MOULTON, BENEDICT, BIES, TOWNSEND, BOYLE, PARISI, NEWCOMER, BERCEAU, MURSAU, SOLETSKI, A. OTT, A. WILLIAMS, FIELDS, GUNDERSON, NELSON, NERISON, SINICKI, GARTHWAITE, OWENS, HIXSON, WOOD, KAUFERT and WASSERMAN. Referred to Committee on Public Health, Senior Issues, Long Term Care and Privacy.

- 1 AN ACT *to amend* 146.82 (2) (a) 8.; and *to create* 20.435 (1) (ae), 255.01 (2m),
- 2 255.01 (2n), 255.04 (3) (c), 255.04 (6), 255.04 (7), 255.04 (8), 255.04 (9) and
- 3 255.04 (10) of the statutes; **relating to:** permitting a researcher, under certain
- 4 conditions, access to cancer information reported to the Department of Health
- 5 and Family Services, prohibiting certain other use or redisclosure of the
- 6 information, creating civil liability for violation of the prohibitions, making an
- 7 appropriation, and providing penalties.

Do not
gen

Analysis by the Legislative Reference Bureau

Insert ✓
analysis

Under current law, hospitals, physicians, and certain laboratories must report to the Department of Health and Family Services (DHFS) information concerning any person who is diagnosed as having cancer or a precancerous condition. Any information that DHFS receives under this requirement that could identify the person or a physician who submits the report is confidential as a patient health care record, except that DHFS may disclose the information to a central tumor registry in another state, if the person who is the subject of the information resides in the other state, or to a national tumor registry.

Beginning July 1, 2008, this bill permits DHFS to disclose otherwise confidential cancer report information to a researcher who requests it, by means of a written application to DHFS, for the purpose of studying cancer, cancer prevention,

SENATE BILL 415

or cancer control or performing other cancer research. The application must include a written protocol for the proposed research, the researcher's professional qualifications, documentation of approval of the research protocol by an institutional review board that meets certain requirements, and any information requested by DHFS. These conditions must be met before DHFS may approve the application and before DHFS may release the information. The bill authorizes DHFS to impose a reasonable fee on a researcher who obtains information. The fee must be commensurate with actual direct costs to DHFS and may be waived by DHFS. Cancer information obtained by DHFS or by a researcher is, under the bill, not subject to open records requirements. The bill specifically prohibits use of the information for a purpose other than for performance of research, disclosure of the information to a person who is not connected with performance of the research, and revealing in the final research product information that may identify a research subject, and creates penalties for violation and intentional violation of the prohibitions. Lastly, the bill creates civil liability to the research subject for any person who negligently or intentionally violates the prohibitions.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert the following amounts for the purposes indicated:

	2007-08	2008-09
20.435 Health and family services, department		
of		
(1) PUBLIC HEALTH SERVICES PLANNING, REGULATION		
AND DELIVERY; STATE OPERATIONS		
(ae) Cancer information	GPR A	-0- 90,800

SECTION 2. 20.435 (1) (ae) of the statutes is created to read:

SENATE BILL 415

Insert 3-1
1 20.435 (1) (ae) *Cancer information*. The amounts in the schedule for cancer
2 information collecting, compiling, and disseminating under s. 255.04.

3 SECTION 3. 146.82 (2) (a) 8. of the statutes is amended to read:

4 146.82 (2) (a) 8. To the department under s. 255.04 and to the persons specified
5 under s. 255.04 (3). The release of a patient health care record under this subdivision
6 shall be limited to the information prescribed by the department under s. 255.04 (2).

7 SECTION 4. 255.01 (2m) of the statutes is created to read:

8 255.01 (2m) "Research" means a systematic investigation through scientific
9 inquiry, including development, testing, and evaluation, that is designed to develop
10 or contribute to generalizable knowledge.

11 SECTION 5. 255.01 (2n) of the statutes is created to read:

12 255.01 (2n) "Researcher" means a person who performs research.

13 SECTION 6. 255.04 (3) (c) of the statutes is created to read:

14 255.04 (3) (c) If all of the following conditions are met, a researcher who
15 proposes to conduct research:

16 1. The researcher applies in writing to the department for approval of access
17 to individually identifiable information under sub. (1) or (5) that is necessary for
18 performance of the proposed research and the department approves the application.

19 An application under this subdivision shall include all of the following:

20 a. A written protocol to perform research.

21 b. The researcher's professional qualifications to perform the proposed
22 research.

23 c. Documentation of approval of the research protocol by an institutional
24 review board of a domestic institution that has a federalwide assurance issued by the

approved

SENATE BILL 415**SECTION 6**

1 office of human research protections of the federal department of health and human
2 services.

3 d. Any other information requested by the department.

4 2. The proposed research is for the purpose of studying cancer, cancer
5 prevention, or cancer control or performing other cancer research.

6 **SECTION 7.** 255.04 (6) of the statutes is created to read:

7 255.04 (6) The department may ^{charge} impose a reasonable fee on a researcher who,
8 under sub. (3) (c), obtains information under sub. (1) or (5). ^{for disclosing information to} The fee shall be
9 commensurate with the actual direct costs to the department that are associated
10 with collecting, compiling, and disseminating the information to the researcher and
11 may be waived by the department.

12 **SECTION 8.** 255.04 (7) of the statutes is created to read:

13 255.04 (7) Information obtained by the department under sub. (1) or (5) or
14 obtained by a person under sub. (3) (c) is not subject to inspection, copying, or receipt
15 under s. 19.35 (1).

16 **SECTION 9.** 255.04 (8) of the statutes is created to read:

17 255.04 (8) No person to whom information is disclosed under sub. (3) (c) may
18 do any of the following:

19 (a) Use the information for a purpose other than for the performance of
20 research as specified in the application under sub. (3) (c) 1., as approved by the
21 department.

22 (b) Disclose the information to a person who is not connected with performance
23 of the research.

24 (c) Reveal in the final research product information that may identify an
25 individual whose information is disclosed under sub. (3) (c).

SENATE BILL 415

1 **SECTION 10.** 255.04 (9) of the statutes is created to read:

2 255.04 (9) Whoever violates sub. (8) (a), (b), or (c) is liable to the subject of the
3 information for actual damages and costs, plus exemplary damages of up to \$1,000
4 for a negligent violation and up to \$5,000 for an intentional violation.

5 **SECTION 11.** 255.04 (10) of the statutes is created to read:

6 255.04 (10) (a) Whoever intentionally violates sub. (8) (a), (b), or (c) may be
7 fined not more than \$15,000 or imprisoned for not more than one year in the county
8 jail or both.

9 (b) Any person who violates sub. (8) (a), (b), or (c) may be required to forfeit not
10 more than \$100 for each violation. Each day of continued violation constitutes a
11 separate offense, except that no day in the period between the date on which a
12 request for a hearing is filed under s. 227.44 and the date of the conclusion of all
13 administrative and judicial proceedings arising out of a decision under this
14 paragraph constitutes a violation.

15 (c) The department may directly assess forfeitures under par. (b). If the
16 department determines that a forfeiture should be assessed for a particular violation
17 or for failure to correct the violation, the department shall send a notice of
18 assessment to the alleged violator. The notice shall specify the alleged violation of
19 the statute and the amount of the forfeiture assessed and shall inform the alleged
20 violator of the right to contest the assessment under s. 227.44.

21 **SECTION 12. Nonstatutory provisions.**

22 (1) **CANCER INFORMATION.** The authorized FTE positions for the department of
23 health and family services are increased by 1.0 GPR position on July 1, 2008, to be
24 funded from the appropriation under section 20.435 (1) (ae) of the statutes, as

SENATE BILL 415

SECTION 12

1 created by this act, for the purpose of cancer information collecting, compiling, and
2 disseminating.

3 **SECTION 13. Effective date.**

4 (1) This act takes effect on July 1, 2008.

5 (END)

Insert 6-3

**2009-2010 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0956/?ins
TJD:.....

INSERT ANALYSIS

✓ **HEALTH AND HUMAN SERVICES**

✓ **HEALTH**

Under current law, with few exceptions, a patient's health information must remain confidential unless the patient gives informed consent to release that information. Hospitals, physicians, and certain laboratories, however, must report information concerning any person diagnosed as having cancer or a precancerous condition to DHS. The department may not disclose any information that could identify the patient except to the national tumor registry or to a central tumor registry in another state, if the patient resides in the other state. that to DHS

This bill allows DHS to disclose otherwise confidential cancer report information to certain researchers. To obtain the information, a researcher must submit an application with a written research protocol, the researcher's qualifications, documentation of approval of the protocol by an institutional review board, and any information requested by DHS. The proposed research must study cancer, cancer prevention or cancer control or perform other cancer research. DHS may charge a fee for providing information to the researcher. * requests

DHS The bill prohibits the researcher from disclosing the cancer information obtained from the department except in certain circumstances. Anyone who discloses a patient's confidential cancer information is liable to that patient for actual damages and costs plus exemplary damages of up to \$1000 for a negligent violation and up to \$5000 for an intentional violation. Anyone disclosing a patient's confidential information is subject to a criminal penalty of a \$15,000 fine or imprisonment of not more than one year in the county jail or both and is subject to a forfeiture assessed by DHS of up to \$100 for each violation. *

INSERT 3-1

SECTION 1. 20.435 (1) (gp) of the statutes is created to read:

20.435 (1) (gp) *Cancer information.* All moneys received from fees collected for access to cancer registry information under s. 255.04 for collecting, compiling, and disseminating cancer information under s. 255.04.

****NOTE: This SECTION involves a change in an appropriation that must be reflected in the revised schedule in s. 20.005, stats. ✓

INSERT 6-3

****NOTE: When previously introduced, this draft had a delayed effective date. ✓
Would you like an effective date different from ~~that of~~ the rest of the budget bill?

For this draft that is.

For the provisions in this draft



State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0956/1²

TJD:wlj:rs

stays ↑
RMNR

In: 1130/09

DOA:.....Palchik, BB0237 - Cancer researcher access to cancer registry data

FOR 2009-11 BUDGET -- NOT READY FOR INTRODUCTION

Do Not Gen

- 1 AN ACT ...; **relating to:** permitting a researcher, under certain conditions, access
2 to cancer information reported to the Department of Health and Family
3 Services, prohibiting certain other use or redisclosure of the information,
4 creating civil liability for violation of the prohibitions, making an
5 appropriation, and providing penalties.

Analysis by the Legislative Reference Bureau

HEALTH AND HUMAN SERVICES

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documentation of approval of the protocol by an institutional review board, and any information that DHS requests. The proposed research must study cancer, cancer prevention, or cancer control. DHS may charge a fee for providing information to the researcher.

The bill prohibits the researcher from disclosing the cancer information obtained from DHS except in certain circumstances. Anyone who discloses a patient's confidential cancer information is liable to that patient for actual damages and costs plus exemplary damages of up to \$1,000 for a negligent violation and up to \$5,000 for an intentional violation. Anyone disclosing a patient's confidential information is subject to a fine of \$15,000 or imprisonment of not more than one year in the county jail or both and is subject to a forfeiture assessed by DHS of up to \$100 for each violation.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 20.435 (1) (gp) of the statutes is created to read:

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3 access to cancer registry information under s. 255.04 for collecting, compiling, and
4 disseminating cancer information under s. 255.04.

 ****NOTE: This SECTION involves a change in an appropriation that must be reflected in the revised schedule in s. 20.005, stats.

5 **SECTION 2.** 146.82 (2) (a) 8. of the statutes is amended to read:

6 146.82 (2) (a) 8. To the department under s. 255.04 and to the persons specified
7 under s. 255.04 (3). The release of a patient health care record under this subdivision
8 shall be limited to the information prescribed by the department under s. 255.04 (2).

9 **SECTION 3.** 255.01 (2m) of the statutes is created to read:

1 255.01 (2m) "Research" means a systematic investigation through scientific
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3 or contribute to generalizable knowledge.

4 **SECTION 4.** 255.01 (2n) of the statutes is created to read:

5 255.01 (2n) "Researcher" means a person who performs research.

6 **SECTION 5.** 255.04 (3) (c) of the statutes is created to read:

7 255.04 (3) (c) A researcher who proposes to conduct research, if all of the
8 following conditions are met:

9 1. The researcher applies in writing to the department for approval of access
10 to individually identifiable information under sub. (1) or (5) that is necessary for
11 performance of the proposed research, and the department approves the application.
12 An application under this subdivision shall include all of the following:

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16 c. Documentation of approval of the research protocol by an institutional
17 review board of a domestic institution that has a federalwide assurance approved by
18 the office for human research protections of the federal department of health and
19 human services.

20 d. Any other information requested by the department.

21 2. The proposed research is for the purpose of studying cancer, cancer
22 prevention, or cancer control.

23 **SECTION 6.** 255.04 (6) of the statutes is created to read:

24 255.04 (6) The department may charge a reasonable fee for disclosing
25 information to a researcher under sub. (3) (c).

1 **SECTION 7.** 255.04 (7) of the statutes is created to read:

2 255.04 (7) Information obtained by the department under sub. (1) or (5) or
3 obtained by a person under sub. (3) (c) is not subject to inspection, copying, or receipt
4 under s. 19.35 (1).

5 **SECTION 8.** 255.04 (8) of the statutes is created to read:

6 255.04 (8) No person to whom information is disclosed under sub. (3) (c) may
7 do any of the following:

8 (a) Use the information for a purpose other than for the performance of
9 research as specified in the application under sub. (3) (c) 1., as approved by the
10 department.

11 (b) Disclose the information to a person who is not connected with performance
12 of the research.

13 (c) Reveal in the final research product information that may identify an
14 individual whose information is disclosed under sub. (3) (c).

15 **SECTION 9.** 255.04 (9) of the statutes is created to read:

16 255.04 (9) Whoever violates sub. (8) (a), (b), or (c) is liable to the subject of the
17 information for actual damages and costs, plus exemplary damages of up to \$1,000
18 for a negligent violation and up to \$5,000 for an intentional violation.

19 **SECTION 10.** 255.04 (10) of the statutes is created to read:

20 255.04 (10) (a) Whoever intentionally violates sub. (8) (a), (b), or (c) may be
21 fined not more than \$15,000 or imprisoned for not more than one year in the county
22 jail or both.

23 (b) Any person who violates sub. (8) (a), (b), or (c) may be required to forfeit not
24 more than \$100 for each violation. Each day of continued violation constitutes a
25 separate offense, except that no day in the period between the date on which a

1 request for a hearing is filed under s. 227.44 and the date of the conclusion of all
2 administrative and judicial proceedings arising out of a decision under this
3 paragraph constitutes a violation.

4 (c) The department may directly assess forfeitures under par. (b). If the
5 department determines that a forfeiture should be assessed for a particular violation
6 or for failure to correct the violation, the department shall send a notice of
7 assessment to the alleged violator. The notice shall specify the alleged violation of
8 the statute and the amount of the forfeiture assessed and shall inform the alleged
9 violator of the right to contest the assessment under s. 227.44.

****NOTE: For the provisions in this draft would you like an effective date different
from that of the rest of the budget bill?

10

(END)



State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0956/2

TJD:wlj:jf

DOA:.....Palchik, BB0237 - Cancer researcher access to cancer registry data
FOR 2009-11 BUDGET -- NOT READY FOR INTRODUCTION

1 **AN ACT** ...; **relating to:** permitting a researcher, under certain conditions, access
2 to cancer information reported to the Department of Health and Family
3 Services, prohibiting certain other use or redisclosure of the information,
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 ****NOTE: This SECTION involves a change in an appropriation that must be reflected in the revised schedule in s. 20.005, stats.

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6 146.82 (2) (a) 8. To the department under s. 255.04 and to the persons specified
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8 shall be limited to the information prescribed by the department under s. 255.04 (2).

9 **SECTION 3.** 255.01 (2m) of the statutes is created to read:

1 255.01 **(2m)** "Research" means a systematic investigation through scientific
2 inquiry, including development, testing, and evaluation, that is designed to develop
3 or contribute to generalizable knowledge.

4 **SECTION 4.** 255.01 (2n) of the statutes is created to read:

5 255.01 **(2n)** "Researcher" means a person who performs research.

6 **SECTION 5.** 255.04 (3) (c) of the statutes is created to read:

7 255.04 **(3)** (c) A researcher who proposes to conduct research, if all of the
8 following conditions are met:

9 1. The researcher applies in writing to the department for approval of access
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11 performance of the proposed research, and the department approves the application.
12 An application under this subdivision shall include all of the following:

13 a. A written protocol to perform research.

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15 research.

16 c. Documentation of approval of the research protocol by an institutional
17 review board of a domestic institution that has a federalwide assurance approved by
18 the office for human research protections of the federal department of health and
19 human services.

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21 2. The proposed research is for the purpose of studying cancer, cancer
22 prevention, or cancer control.

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24 255.04 **(6)** The department may charge a reasonable fee for disclosing
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1 **SECTION 7.** 255.04 (7) of the statutes is created to read:

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5 **SECTION 8.** 255.04 (8) of the statutes is created to read:

6 255.04 (8) No person to whom information is disclosed under sub. (3) (c) may
7 do any of the following:

8 (a) Use the information for a purpose other than for the performance of
9 research as specified in the application under sub. (3) (c) 1., as approved by the
10 department.

11 (b) Disclose the information to a person who is not connected with performance
12 of the research.

13 (c) Reveal in the final research product information that may identify an
14 individual whose information is disclosed under sub. (3) (c).

15 **SECTION 9.** 255.04 (9) of the statutes is created to read:

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7 assessment to the alleged violator. The notice shall specify the alleged violation of
8 the statute and the amount of the forfeiture assessed and shall inform the alleged
9 violator of the right to contest the assessment under s. 227.44.

10 (END)